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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LILLING, HERBERT J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/886,254

Applicant(s)

GUSYATINER ET AL.

Examiner

HERBERT J LILLING

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 7-22 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 12-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 7, 8, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 9 and 12-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. Receipt is acknowledged of the amendment filed July 18, 2002.

2. Claims 7-22 are now pending in this application.

Claims 1-6 have been cancelled.

3. Claims 7,8, 10 and 11 are drawn to the elected invention.

Claims 9 and 12-22 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to the nonelected inventions, there being no allowable generic or linking claim

4. The rejection of claims under 35 U.S.C. 101 have been withdrawn in view of the new claims.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-8, 10-11 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor is not enabled in view of the lack of the microorganism is not available to one skilled in the art to make and use commensurate in scope with the best mode as indicated by Applicant in the examples in the specification, see the following paragraphs:

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It is apparent that the best mode to practice the claimed invention(s) as recited in the claims requires strain(s) which are not known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strain(s). See 37 C. F. R. 1.802.

The specification does not provide a repeatable method for obtaining the strain(s) and it does not appear to be a readily available material. Deposit of strain(s) would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- b) all restrictions imposed by the depositor on the availability to the public of the deposited material **will be irrevocably** removed upon the granting of a patent;
- c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- d) a viability statement in accordance with the provisions of 37 CFR 1.807;

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and
e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

The statement as submitted on pages 4-5 as to the availability of the two deposited strains are appropriate but Applicant has failed to submit the identifying information as noted in the above paragraph:

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

See the following paragraph pertaining to the lack of the identifying information:

The language of the claims must make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds". See, e.g., the following decisions: In re Hammack, 427 F 2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); In re Venezia 530 F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); In re Goffe, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); In re Watson, 517 F 2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); In re Knowlton 481 F 2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: In re Steele, 305 F 2d. 859, 134 USPQ 292 (CCPA 1962); In re Moore 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); In re Merat, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975).

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"The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover."

The Claims fail to comply with the above decisions.

Thus, it is impossible for an appropriate comparison between any claims drawn to a deposited claim or essentially for the broad claims as to the Patentability over any prior art. For the elected claims, Applicant has not presented any deposited claim that is drawn to the elected invention.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 8 and 10-11 are (stand) rejected under 35 U.S.C. 102(b) as anticipated by Reference AW, McQuillen et al. for the same reasons as in the prior action:

The disclosure of the reference teaches a microorganism that is considered to be within the scope of the claimed inventions absent a showing to the contrary, see the following:

It is well settled that if a reference reasonably teaches a product which is identical or substantially identical or are produce by identical or substantially identical process, the PTO can require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product. A rationale given for

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shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products, see In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972); In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977).

Claims 7 and 10 clearly anticipate the claimed inventions. The burden is on Applicant to show that the reference microorganism does not absolutely produce arginine in a medium containing acetic acid or acetate as the lone source. The instant specification only indicates that the strain on page 8 grows poorly but there is absolutely no indication that no arginine was produced. In any event, the burden is on Applicant to show that the reference product is not within the scope of the claimed inventions especially in view of the incomplete compliance with the Rules of Deposit.

7. **No claim is allowed.**

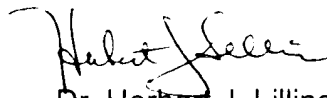
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number is (703) 308-4242 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit 1651
July 25, 2002



Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651